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APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,170	08/20/2001		Philippe Cinquin	CINQUIN-1	1102
7:	590	10/06/2003		EXAMINER	
Arthur L Plev			MARMOR II, CHARLES ALAN		
Duane Morris &	& Hecksc	her			
Suite 100				ART UNIT	PAPER NUMBER
100 College Ro	ad West		3736		
Princeton, NJ 08540				DATE MAILED: 10/06/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

•	Application No.	Applicant(s)						
	09/831,170	CINQUIN ET AL.						
Office Action Summary	Examiner	Art Unit						
	Charles A. Marmor, I							
The MAILING DATE of this communication app ars on the cover sheet with the correspond nce address Period for Reply								
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status								
1) Responsive to communication(s) filed on	·							
2a)☐ This action is FINAL . 2b)⊠ Th	is action is non-final.							
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.								
Disposition of Claims								
4)⊠ Claim(s) <u>1-12</u> is/are pending in the application								
4a) Of the above claim(s) is/are withdrawn from consideration.								
5) Claim(s) is/are allowed.								
6)⊠ Claim(s) <u>1-12</u> is/are rejected.								
7) Claim(s) is/are objected to.								
8) Claim(s) are subject to restriction and/or election requirement. Application Papers								
9)☐ The specification is objected to by the Examine	· ·r							
10)⊠ The drawing(s) filed on <u>20 August 2001</u> is/are: a)□ accepted or b)⊠ objected to by the Examiner.								
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.								
If approved, corrected drawings are required in reply to this Office action.								
12)⊠ The oath or declaration is objected to by the Examiner.								
Priority under 35 U.S.C. §§ 119 and 120								
13)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).								
a)⊠ All b)□ Some * c)□ None of:								
 Certified copies of the priority document 	s have been received	d.						
2.☐ Certified copies of the priority document	2. Certified copies of the priority documents have been received in Application No							
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 								
14) Acknowledgment is made of a claim for domest			I application).					
a) ☐ The translation of the foreign language provisional application has been received. 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.								
Attachment(s)								
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1	5) 🔲 Not	erview Summary (PTO-413) Paper No ice of Informal Patent Application (PT er:						

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DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the means for locating several positions of the femur during motions thereof, the means for imposing a constraint to the center of rotation without immobilizing it; and the calculation means, all recited in claim 12, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 6 is objected to because of the following informalities: in line 1, "a the" apparently should read --the--. Appropriate correction is required.

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Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Regarding claims 1-11, the claims are not enabling because the specification does not provide a full, clear and concise description of how the method is used. For example, in claim 1, the claim is not concise and exact as to in what fashion and by what means is the bone displaced; how the step of "locating several ones of its positions and memorizing them" is performed (e.g. is it done mechanically or intellectually?); how the displacement of the center of rotation is constrained "without immobilizing it"; how the step of "searching a point linked to the referential of said bone" is performed (e.g. is it done mechanically or intellectually?); and what the "optimization criteria" comprises as this terminology does not have well established meaning, leaving doubt as to the technical characteristics to which it refers. As a further example, claim 2 is not concise and exact as to how the step of "searching the invariants of this displacement, taking into account the fact that the center of rotations of the first and second femurs are distant by a substantially constant length" is performed (e.g. is it done mechanically or intellectually?). Similar problems exist in claims 3-11.

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Regarding claim 12, the claim is not enabling because the specification does not provide a full, clear and concise description of how the method is used. No structural elements are disclosed that form the claimed means of the device. The only structural elements disclosed comprise mechanical systems for blocking the thigh and external markers. These structural elements do not constitute an adequate description to enable a person of ordinary skill in the art to make the device as claimed.

- 6. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 7. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1-12, use of the pronouns "it", "its" and "them" render the claims indefinite, as one cannot be certain what each of the aforementioned pronouns refers to.

Further regarding claims 1, 2, 4 and 12, the claim language apparently is contradictory of itself and as such renders the claim indefinite. Particularly, it is why a "method for determining the center of rotation of a bone" is being performed when the claim language suggests or requires that the center of rotation is already known.

Further regarding claim 1, the claim language apparently is contradictory of itself and as such renders the claim indefinite. Particularly, it is unclear how the center of rotation can be restrained without immobilizing it to some degree.

Claim 1 recites the limitation "the referential" in line 8. There is insufficient antecedent basis for this limitation in the claim. There is no referential recited in the claim prior to this recitation.

Further regarding claim 1, since the term "optimization criterion" lacks a well established and recognized meaning, the metes and bounds of the limitation are indefinite.

Claims 2, 4, 6, 7 and 9 recite the limitation "the method for determining the center of rotation of a femur with respect to the iliac bone of claim 1" in lines 1-2. There is insufficient antecedent basis for this limitation in the claims. There is no such method recited in claim 1.

Claim 2 recites the limitation "the invariants" in line 7. There is insufficient antecedent basis for this limitation in the claim. There are no invariants recited in the claims prior to this recitation.

Claim 3 recites the limitation "each measurement" in line 2. There is insufficient antecedent basis for this limitation in the claim. There are no measurements recited in the claims prior to this recitation.

Further regarding claim 4, it is unclear what point the limitation "searching this point" is intended to refer to.

Further regarding claim 4, since the term "optimization method" lacks a well established and recognized meaning, the metes and bounds of the limitation are indefinite.

Further regarding claim 4, the limitation "a trajectory which is clearly mathematically distinct" in line 5 renders claim indefinite. The limitation "clearly mathematically distinct" lacks a well established and recognized meaning such that the metes and bounds of the limitation are indefinite.

Further regarding claim 6, the phrase "can be" renders the claim indefinite. It is unclear whether the thigh motion is decomposed or if the thigh motion is merely capable of being decomposed.

Further regarding claim 6, the limitation "decomposed in several elementary motions" in lines 4-5 renders claim indefinite. The limitation "elementary motions" lacks a well established and recognized meaning such that the metes and bounds of the limitation are indefinite.

Claim 6 recites the limitation "each of the estimations" in line 9. There is insufficient antecedent basis for this limitation in the claim. There are no estimations recited in the claims prior to this recitation.

Further regarding claim 6, since the terms "optimal" and "optimized" lack a well established and recognized meaning, the metes and bounds of the limitation are indefinite.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 7 recites the broad recitation "as simple a

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trajectory as possible", and the claim also recites "in particular, no loops" which is the narrower statement of the range/limitation.

Further regarding claim 7, it is unclear what point the limitation "searching this point" is intended to refer to.

Further regarding claim 7, since the term "optimization method" lacks a well established and recognized meaning, the metes and bounds of the limitation are indefinite.

Further regarding claim 7, since the term "as simple as possible" lacks a well established and recognized meaning, the metes and bounds of the limitation are indefinite.

Further regarding claim 7, since the term "mathematically simple" lacks a well established and recognized meaning, the metes and bounds of the limitation are indefinite.

Further regarding claim 8, the phrase "can be" renders the claim indefinite. It is unclear whether the thigh motion is decomposed or if the thigh motion is merely capable of being decomposed.

Further regarding claim 8, the limitation "decomposed in several elementary motions" in lines 2-3 renders claim indefinite. The limitation "elementary motions" lacks a well established and recognized meaning such that the metes and bounds of the limitation are indefinite.

Claim 8 recites the limitation "the optimized distance" in line 5. There is insufficient antecedent basis for this limitation in the claim. There is no optimized distance recited in the claims prior to this recitation.

Claim 8 recites the limitation "each of the estimations" in line 7. There is insufficient antecedent basis for this limitation in the claim. There are no estimations recited in the claims prior to this recitation.

Further regarding claim 9, the limitation "a succession of elementary motions" in line 4 renders claim indefinite. The limitation "elementary motions" lacks a well established and recognized meaning such that the metes and bounds of the limitation are indefinite.

Further regarding claim 9, since the term "high" lacks a well established and recognized meaning, the metes and bounds of the limitation are indefinite.

Further regarding claim 10, since the term "elementary motions" lacks a well established and recognized meaning, the metes and bounds of the limitation are indefinite.

Further regarding claim 10, since the term "small" lacks a well established and recognized meaning, the metes and bounds of the limitation are indefinite.

Further regarding claim 11, since the term "elementary motions" lacks a well established and recognized meaning, the metes and bounds of the limitation are indefinite.

Further regarding claim 12, the claim language apparently is contradictory of itself and as such renders the claim indefinite. Particularly, it is unclear how the center of rotation can be restrained without immobilizing it to some degree.

Claim 12 recites the limitation "the referential" in lines 8-9. There is insufficient antecedent basis for this limitation in the claim. There is no referential recited in the claim prior to this recitation.

Further regarding claim 12, since the term "minimization criterion" lacks a well established and recognized meaning, the metes and bounds of the limitation are indefinite. It also is unclear why claim 12 utilizes a minimization criterion while the remaining claims utilize an optimization criterion.

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Claim Rejections - 35 USC § 102

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8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on

sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Dance et al.

('075). Dance et al. teach a method and apparatus for determining the center of rotation of a

bone in a revolute joint where the bone is displaced; several of its positions are located and

memorized; the center of rotation is constrained without immobilizing it; and a point linked to

the referential of the bone is searched for which a optimization or minimization criterion is

reached while taking into account the constraint.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's

disclosure. The prior art of record apparently does not teach a method for determining the center

of rotation of a femur with respect to the iliac bone as claimed by Applicant in claims 2-11.

Dance et al. ('566) teach a method and apparatus for the alignment of a femoral knee prosthesis.

Peterson et al. ('590) teach a surgical laser beam-based alignment system and method. Bainville

et al. ('437) teach a method and system for determining the fixation point on the femur of

crossed ligament of the knee. Benson ('050) teaches a method and apparatus for determining

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offset-inset distances in a hip. Cinquin et al. ('475) teach a process and device for the preoperative determination of the positioning data of endoprosthetic parts.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Charles A. Marmor, II Primary Examiner Art Unit 3736

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September 30, 2003